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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,113	02/26/2004	Peter Francis Joseph O'Hare	5759-67874	8100

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,113	O'HARE ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Claims 10-11 and 13-15 recite "any one of the agents (a) and/or (b)" in regard to, respectively, the method steps and compositions of Claims 1 and 6-8. However, the method steps and compositions of Claims 1(a), 6(a), 7(a) and 8(a) recite no such agent. Therefore, it is understood that the agents of Claims 10-11 and 13-15 refer to the agents recited in Claims 1(b), 6(b), 7(b) and 8(b).

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of making a medicament composition comprising a nucleic acid encoding an amino acid sequence with the transport function of herpesviral VP22 protein functionally coupled to an amino acid sequence encoding a protein or peptide which can regulate cell cycle progression and an agent to stimulate cell death, said composition, and a method of reducing proliferation in cells using said composition, classified in class 514, subclass 44.

2. **Should Applicant elect Invention I, a species election is required under 35 U.S.C. 121**. Currently, Claims 1 and 6-8 of this application recite a plurality of disclosed, patentably distinct agent functionality categories that can stimulate cell death that prohibit proper examination of these claims. Therefore, election is required under 35 U.S.C. 121 of one agent functionality category that stimulates cell death consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted, wherein the agent, specifically:

i) induces cell cycle arrest,

ii) is a cytotoxic chemotherapeutic drug commonly used as part of a treatment of malignant disease,

iii) is a DNA damaging agent,

iv) is an agent which increases cellular sensitivity to DNA damage, or

v) is cytotoxic amounts of radiation.

In the instant case, each species is agent is a structurally and mechanistically distinct composition that is independent and distinct from the other agents. The radiation effects its biological activity via a distinctly different mechanism than an agent that induces cell cycle arrest. Similarly, a cytotoxic chemotherapeutic drug commonly used as part of a treatment of malignant disease may be a chemical compound that acts by a completely different mechanism than a DNA damaging agent. For example, cisplatin and taxol affect the cytoskeleton; whereas, ethylmethanesulphonate (EMS) and ethylnitrosourea (ENU) are well-known in the art to damage DNA.

A search for one agent mechanism would not be co-extensive with a search for another agent mechanism. Further, a reference rendering a cytotoxic chemotherapeutic drug commonly used as part of a treatment of malignant disease as anticipated or obvious over the prior art would not necessarily also render a novel DNA damaging agent as anticipated or obvious over the prior art. Similarly, a finding that an agent that induces cell cycle arrest was novel and unobvious over the prior art would not necessarily extend to a finding that cytotoxic amounts of radiation was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed agent functionality categories that can stimulate cell death species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable is considered nonresponsive unless accompanied by an election. Failure to elect a species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant elect Invention I and an export functionality category from (i)-(iii) above, a further species election is required under 35 U.S.C. 121. Currently, Claim 10 of this application is generic to a plurality of disclosed, patentably distinct agents that can prevent cell export that prohibit proper examination of this claim. Therefore, election is required under 35 U.S.C. 121 of one agent that can prevent cell export consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, specifically:

iv) an inhibitor of the multi-drug resistance protein, as recited in Claim 11,

v) an Acf protein, as recited in Claim 11, or

vi) an antisense molecule, as recited in Claim 12.

In the instant case, each species is agent is a structurally distinct composition that is independent and distinct from the other agents. The antisense molecule effects its biological activity via a distinctly different mechanism than the Acf protein. Similarly, the inhibitor of the multi-drug resistance protein may be a chemical compound that acts protein by a completely different mechanism than the Acf protein.

A search for an antisense molecule would not be co-extensive with a search for an Acf protein. Further, a reference rendering an antisense molecule as anticipated or obvious over the prior art would not necessarily also render a chemical inhibitor of the multi-drug resistance protein as anticipated or obvious over the prior art. Similarly, a finding that an inhibitor of the multi-drug resistance protein was novel and unobvious over the prior art would not necessarily extend to a finding that an antisense molecule was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed agent that can prevent cell export species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims

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SUPERVISORY PATENT EXAMINER

subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect a species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.